REMARKS

In an Office Action mailed March 12, 2004, the Examiner restricted Claims 1-22 into two groups. In reply, Applicants elected with traverse, to prosecute Claims 1-19, 21 and 22 of Group I. Claims 20 has been withdrawn from consideration. Thus, Claims 1-19, 21 and 22 are currently pending. In the instant Office Action, the Examiner has raised several issues, which are set forth by number in the order they are herein addressed:

1) Specification is objected to as allegedly failing to comply with sequence rules, lacking labels for figure views, and lacking an abstract;
2) Claims 1-19, 21 and 22 stand rejected under the judicially created doctrine of obviousness-type double patenting as unpatentable over claims of U.S. Patent No. 5,958,422 to Lomonossoff, in view of Liu *et al.*, Glycoconjugate J, 12:607-617, 1995;
3) Claims 11-15 stand rejected under the judicially created doctrine of obviousness-type double patenting as unpatentable over claims of U.S. Patent No. 5,874,087 to Lomonossoff, in view of Liu *et al.*, Glycoconjugate J, 12:607-617, 1995;
4) Claims 1-10, 17-19, 21 and 22 stand rejected under the judicially created doctrine of obviousness-type double patenting as unpatentable over claims of U.S. Patent No. 5,958,422 to Lomonossoff, in view of Liu *et al.*, Glycoconjugate J, 12:607-617, 1995;
5) Claim 22 stands rejected under 35 U.S.C. § 101, as allegedly being an improper process claim;
6) Claims 1-19, 21 and 22 stand rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite; and
7) Claims 1-19, 21 and 22 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to provide enablement.

Applicants have amended Claims 1, 6, 7, 11, 13, 14 and 19, canceled Claims 2-4, 12 and 22, and introduced new Claims 23-25, in order to further the prosecution of the present application and Applicants' business interests, yet without acquiescing to the Examiner's arguments. Applicants reserve the right to prosecute the original, similar, or broader claims in one or more future application(s). The amendment does not introduce new matter and is not

intended to narrow the scope of any of the claims within the meaning of *Festo*.[1] Applicants hereby request reconsideration of the application in view of the forgoing amendments, terminal disclaimer, and remarks. In addition, Applicants request consideration of the references of the Information Disclosure Statement submitted herein.

1) The Specification Is Proper

The Examiner has objected to the Specification as allegedly failing to comply with sequence rules, lacking labels for figure views, and lacking an abstract. In the first place, the Examiner has indicated that sequence identifiers are required in the Specification and/or the various Figures. Accordingly, Applicants have amended the background, disclosure and legends to Figures 8, 9, 10, 11, 12, 13, and 14 to include sequence identifiers for the listed sequences. In addition, a substitute sequence listing has been provided. Support for the amendment to the legend of Figure 8 can be found in Example 12 directed to insertions in SBMV, which recites "[t]he five constructs shown in Figure 8B contain the insert between coat protein amino acids 251-252, 252-253, 253-254, 254-255, or 255-256" (Specification, at page 24, lines 6 and 7). Similarly, support for the amendment to the legend of Figure 10 can be found in the original text of this legend, as well as in Example 13 directed to insertions in LTSV, which recites "[t]he six constructs shown in Fig.10B contain the epitope sequence between coat protein amino acids 218-219, 219-220, 220-221, 221-222, 222-223 or 223-224" (Specification, at page 25, lines 8-10). Lastly, support for the amendment to the legend of Figure 14 can be found in the original text of this legend, as well as in Example 14 directed to insertions in RCNMV, which recites "[t]he six constructs shown in Fig.14B insert the epitope sequence between coat protein amino acids 221-222, 222-223, 223-224, 224-225, 225-226 or 226-227" (Specification, at page 27, lines 1 and 2).

In the second place, the Examiner has indicated that the Specification is required to contain labels for the multiple views of Figures 3, 10 and 14. Accordingly, Applicants have amended the legends of Figures 3, 10 and 14. Support for the amendment to Figure 3 can be found in Example 3, which describes results from experiments on mice immunized with CVPs in FCA or with CVPs in QS-21 (Specification, at page 17, lines 17-28).

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[1] *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 122 S.Ct. 1831, 1838, 62 USPQ2d 1705, 1710 (2002).

Thirdly, the Examiner has indicated that an abstract on a separate sheet is required, and that the USPTO does not automatically accept the WO cover sheet as an abstract. For this reason, Applicants have specifically directed the Office to insert an abstract on a separate sheet following the claims, the text of which is identical to the abstract listed on the WO cover sheet of the parent application.

Applicants believe that the amendments described above are sufficient to remove the informalities of the Specification, and therefore respectfully request that this objection be withdrawn.

2-4) The Claims Are Nonobvious

The Examiner has rejected Claims 1-19, 21 and 22, under the judicially created doctrine of obviousness-type double patenting as allegedly unpatentable over claims of one or more of U.S. Patent No. 5,874,087 to Lomonossoff, U.S. Patent No. 5,958,422 to Lomonossoff, or U.S. Patent No. 6,110,466 to Lomonossoff, in view of Liu *et al.*, Glycoconjugate J, 12:607-617, 1995. Applicants must respectfully disagree. However, in order to further their business interests and the prosecution of the present application, but without acquiescing to the Examiner's arguments, Applicants herewith file a Terminal Disclaimer (Tab A), to overcome any obviousness type double patenting rejections.

5) The Claims Are Proper

The Examiner has rejected Claim 22 under 35 U.S.C. § 101, as allegedly being an improper process claim, "because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process" (Office Action, page 8). Applicants must respectfully disagree. Nonetheless, Applicants have canceled Claim 22, in order to further the prosecution of the present application and Applicants' business interests, yet without acquiescing to the Examiner's arguments, and while reserving the right to prosecute the original, similar, or broader claims in one or more future application(s).

6) The Claims Are Definite

The Examiner as rejected Claims 1-19, 21 and 22 under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite. Applicants must respectfully disagree. Nonetheless,

Applicants have amended Claims 1, 6, 7, 11, 13, 14, and 19, canceled Claims 2, 4, 12 and 22 and introduced new Claims 23-25, in order to further the prosecution of the present application and Applicants' business interests, yet without acquiescing to the Examiner's arguments, and while reserving the right to prosecute the original, similar, or broader claims in one or more future application(s). In particular, the Examiner has rejected Claim 1 for the recitations "immunogenically active peptide" and "immunogenically effective." Although Applicants disagree that the claim is indefinite, they have amended Claim 1 to recite "modified by insertion of a peptide epitope of a tumour associated mucin at an exposed site in the coat protein in a loop connecting beta sheets." Support for this amendment is found for instance in original Claims 2 and 12, and in the disclosure that teaches "any mucin peptide epitope sequence can be used" and the "sequence is preferably inserted in that part of the plant viral nucleic acid which codes for an exposed region of the coat protein" (Specification, at page 23, lines 4 and 5, and at page 10, lines 24 and 25). As the limitations of dependent Claims 2 and 12 have been incorporated into independent Claim 1, these dependent claims have been canceled.

Moreover, the Examiner has rejected Claim 4 for containing both a broad and a narrow range. Although, Applicants disagree that the claim is indefinite, they have canceled Claim 4, without prejudice.

The Examiner has rejected Claim 6 for containing the recitations "the 20 amino acid repeat" and "derived." Although Applicants disagree that the claim is indefinite, they have amended Claim 6 to recite "the insert is a peptide comprising at least five amino acids of the 20 amino acid repeat set forth in SEQ ID NO:1." Support for this amendment is found for instance in the disclosure, which teaches the "peptide preferably contains 5 or more amino acids" and "repeating sequences of the 20 amino acid sequence . . . (SEQ ID No.1) are preferred . . . [and a] repeating partial sequence . . . is particularly preferred" (Specification, at page 9, lines 28 and 29, and at page 10 lines 2-4).

In addition, the Examiner has rejected Claim 7 for containing both a broad and a narrow range. Although, Applicants respectfully disagree that the claim is indefinite, they have amended Claim 7, and introduced new Claim 24 to read upon the 16mer of SEQ ID NO:6, and the 23mer of SEQ ID NO:7, respectively. Similarly, Applicants have introduced new Claims 24 and 25 to read upon SEQ ID NO:2, and SEQ ID NO:3, respectively.

The Examiner has also rejected Claim 11 for containing the phrase "the tumour-associated mucin peptide" without sufficient antecedent basis. Although, Applicants respectfully disagree that the claim is indefinite, they have amended Claim 11 to recite "the peptide epitope of a tumour associated mucin" for which antecedent basis is provided in amended Claim 1. In addition, Applicants have amended Claims 13 and 14 to recite simply "peptide epitope" for which antecedent basis is provided in amended Claim 11.

Furthermore, the Examiner has rejected Claim 19 for the recitation "substantially." Although, Applicants respectfully disagree that the claim is indefinite, they have amended Claim 19 to recite "said vaccine being free from exogenous adjuvant." Support for this amendment is found for instance in Example 7 of the disclosure entitled "exogenous adjuvant is not required for CVPs of the present invention" (Specification, at page 20, lines 12-19).

Lastly, the Examiner has rejected Claim 22 for being a method/process claim lacking any steps. As described in section 5, Applicants have canceled Claim 22, without prejudice.

As the amended claims are definite, Applicants respectfully request that this rejection be withdrawn.

7) The Claims Are Enabled

The Examiner has rejected Claims 1-19, 21 and 22 under 35 U.S.C. § 112, first paragraph, as allegedly failing to provide enablement. In particular, the Examiner states:

> while being enabling for the chimeric virus particle of claim 1 and method of claim 11 wherein the peptide of the tumor-associated mucin is inserted in a loop connecting beta sheets and is free from flanking direct nucleotide sequence repeats, does not reasonably provide enablement for the claimed particle and method wherein the peptide is inserted at other sites in the coat protein (Office Action, pages 11-13).

Applicants must respectfully disagree. Nonetheless, Applicants have amended Claim 1, and canceled Claims 2-4, and 12, in order to further the prosecution of the present application and Applicants' business interests, yet without acquiescing to the Examiner's arguments, and while reserving the right to prosecute the original, similar, or broader claims in one or more future application(s). In particular, Applicants have amended Claim 1 to recite the insertion of a peptide epitope "at an exposed region in the coat protein in a loop connecting beta sheets," as described above in section 1.

In making this enablement rejection, the Examiner has cited Porta *et al.,* Virology 202:949-955, as evidence that "[n]either the prior art nor the specification teach CVPs in which the foreign peptide can be inserted into other sites of the coat protein," with other sites apparently encompassing positions comprising *flanking direct nucleotide sequence repeats* within a loop connecting beta sheets. However, as disclosed in this citation, the original CVPs of Porta *et al.* (produced from pMT7-FMDV-1) comprising a foot-and-mouth disease virus (FMDV) epitope in a CPMV loop connecting beta sheets flanked by eight base pair direct repeats, *retained* the ability to infect plants and to produce a capsid protein (S protein) containing the FMDV epitope (*See,* Porta *et al.,* page 949, second paragraph of introduction). That these exemplary CVPs having an epitope flanked by repeats have a competitive disadvantage in regard to wild type CPMV is irrelevant to the issue of enablement, as such CVPs simply reflect a preferred embodiment of the present invention. Support for this assertion is found in the instant application as filed, which teaches "[a]ny of the loops which lie between the β-strands can be used for insertion of foreign epitopes, but the insertions are made such that the additions are exposed on either the internal or external surface of the virus and such that assembly of the coat protein subunits and the infectivity of the virus are *not abolished*" (Specification, at page 5, lines 2-5).

As the amended claims are enabled, Applicants respectfully request that this rejection be withdrawn.

CONCLUSION

Applicants respectfully request that a timely Notice of Allowance be issued in this case. However, should the Examiner believe that a telephone interview would aid in the prosecution of this application, Applicants encourage the Examiner to call the undersigned collect.

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